

PPTA Statement on Update on Safety of Albumin

FDA Blood Products Advisory Committee July 21, 2005

The Plasma Protein Therapeutics Association (PPTA) appreciates actions taken by the FDA and the Blood Products Advisory Committee (BPAC) with respect to the safety of albumin.

In December 2004, PPTA requested that FDA reconsider its 1998 advice to healthcare providers regarding the safety of albumin in critically ill patients. The 1998 action was taken in response to publication of a meta analysis of studies by the Cochrane Injuries Group. PPTA asked FDA to reconsider its position on albumin based on the 2004 published Saline v. Albumin Fluid Evaluation (SAFE) study. FDA included the topic of albumin safety in the next scheduled BPAC meeting agenda, which was held on March 17, 2005.

FDA invited a principal investigator of the SAFE study to present findings before the BPAC. Based on data in the SAFE study, the BPAC voted unanimously that the SAFE study had resolved prior safety concerns raised by the Cochrane Group. On May 16, 2005, FDA posted an update to its 1998 correspondence that revised previous advice regarding the safety of albumin administration in critically ill patients.

PPTA commends FDA and the BPAC for its prompt response to PPTA's request and its willingness to revisit the albumin safety issue based on updated information.

The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.